

108TH CONGRESS  
2D SESSION

# S. 2487

To amend part D of title XVIII of the Social Security Act to ensure that every medicare beneficiary has access to a medicare administered prescription drug plan option, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JUNE 2, 2004

Mr. DAYTON introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To amend part D of title XVIII of the Social Security Act to ensure that every medicare beneficiary has access to a medicare administered prescription drug plan option, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4       (a) SHORT TITLE.—This Act may be cited as the  
5       “Right Prescription for Seniors Act of 2004”.

6       (b) TABLE OF CONTENTS.—The table of contents of  
7       this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Establishment of medicare operated plan option.

Sec. 3. Negotiating fair prices for medicare prescription drugs.

Sec. 4. Importation of prescription drugs.

Sec. 5. Limitation on prescription drug benefits of Members of Congress.

1 **SEC. 2. ESTABLISHMENT OF MEDICARE OPERATED PLAN**

2 **OPTION.**

3 (a) IN GENERAL.—Section 1860D–11(g) of the So-  
 4 cial Security Act, as added by section 101(a) of the Medi-  
 5 care Prescription Drug, Improvement, and Modernization  
 6 Act of 2003 (Public Law 108–173), is amended to read  
 7 as follows:

8 “(g) MEDICARE OPERATED PLAN OPTION.—

9 “(1) IN GENERAL.—Separate from the bidding  
 10 process under subsection (b), the Secretary shall  
 11 provide for the offering in each PDP region of a  
 12 medicare operated plan option (as defined in para-  
 13 graph (4)) and shall enter into negotiations with  
 14 pharmaceutical manufacturers to reduce the pur-  
 15 chase cost of covered part D drugs for eligible part  
 16 D individuals in accordance with paragraph (2).

17 “(2) NEGOTIATIONS.—The Secretary shall ne-  
 18 gotiate with pharmaceutical manufacturers with re-  
 19 spect to the purchase price of covered part D drugs  
 20 and shall encourage the use of more affordable  
 21 therapeutic equivalents to the extent such practices  
 22 do not override medical necessity as determined by  
 23 the prescribing physician. To the extent practicable  
 24 and consistent with the previous sentence, the Sec-

retary shall implement strategies similar to those used by other Federal purchasers of prescription drugs, and other strategies, to reduce the purchase cost of covered part D drugs.

“(3) MEDICARE OPERATED PLAN OPTION.—For purposes of this part, the term ‘medicare operated plan option’ means a prescription drug plan that offers coverage similar to the standard prescription drug coverage and access to negotiated prices described in section 1860D–2(a)(1)(A) and does not include any supplemental prescription drug coverage, except that such plan shall provide continuous coverage and shall not have a coverage gap.

“(4) MONTHLY BENEFICIARY PREMIUM.—

“(A) IN GENERAL.—Except as provided in section 1860D–13(b) (relating to late enrollment penalty) and subject to section 1860D–14 (relating to low-income assistance), the monthly beneficiary premium to be charged under the medicare operated plan option shall be—

“(i) for months in 2006, \$35; and

“(ii) for months in a subsequent year,  
the lesser of—

“(I) the amount determined  
under this paragraph for months in

1 the previous year, increased by the  
 2 annual percentage increase described  
 3 in subparagraph (B) for the year in-  
 4 volved; or

5 “(II) in the case of months in  
 6 years prior to 2014, the specified  
 7 amount (as defined in subparagraph  
 8 (C)).

9 “(B) ANNUAL PERCENTAGE INCREASE.—  
 10 The annual percentage increase specified in this  
 11 paragraph for a year is equal to the annual per-  
 12 centage increase in average per capita aggre-  
 13 gate expenditures for covered drugs in the  
 14 United States for beneficiaries under this title,  
 15 as determined by the Administrator for the 12-  
 16 month period ending in July of the previous  
 17 year.

18 “(C) SPECIFIED AMOUNT.—For purposes  
 19 of the paragraph, the term ‘specified amount’  
 20 means—

21 “(i) for months in 2007, \$37;

22 “(ii) for months in 2008, \$40;

23 “(iii) for months in 2009, \$43;

24 “(iv) for months in 2010, \$46;

25 “(v) for months in 2011, \$51;

1 “(vi) for months in 2012, \$54; and

2 “(vii) for months in 2013, \$59.

3 “(5) NO AFFECT ON ACCESS REQUIREMENTS.—

4 The medicare operated plan option shall be in addi-  
5 tion to the plans required under subsection (d)(1)”.  
6

6 (b) CONFORMING AMENDMENTS.—

7 (1) Section 1860D–3 of the Social Security Act,  
8 as added by section 101(a) of the Medicare Prescrip-  
9 tion Drug, Improvement, and Modernization Act of  
10 2003 (Public Law 108–173), is repealed.

11 (2) Section 1860D–11(f) of the Social Security  
12 Act, as added by section 101(a) of the Medicare Pre-  
13 scription Drug, Improvement, and Modernization  
14 Act of 2003 (Public Law 108–173), is amended—

15 (A) by striking paragraph (1) and insert-  
16 ing the following:

17 “(1) CONDITIONS FOR APPROVAL OF LIMITED  
18 RISK PLANS.—

19 “(A) IN GENERAL.—The Secretary may  
20 only approve a limited risk plan (as defined in  
21 paragraph (4)(A)) for a PDP region if the ac-  
22 cess requirements under subparagraph (B)  
23 would not be met for the region but for the ap-  
24 proval of such a plan.

1 “(B) ENSURING ACCESS TO A CHOICE OF  
2 COVERAGE.—

3 “(i) CHOICE OF AT LEAST TWO PLANS  
4 IN EACH AREA.—The Secretary shall en-  
5 sure that each part D eligible individual  
6 has available, consistent with clause (ii), a  
7 choice of enrollment in at least 2 quali-  
8 fying plans (as defined in clause (iii)) in  
9 the area in which the individual resides, at  
10 least one of which is a prescription drug  
11 plan.

12 “(ii) REQUIREMENT FOR DIFFERENT  
13 PLAN SPONSORS.—The requirement in  
14 clause (i) is not satisfied with respect to an  
15 area if only one entity offers all the quali-  
16 fying plans in the area.

17 “(iii) QUALIFYING PLAN DEFINED.—  
18 For purposes of this section, the term  
19 ‘qualifying plan’ means—

20 “(I) a prescription drug plan; or

21 “(II) an MA–PD plan described  
22 in section 1851(a)(2)(A)(i) that pro-  
23 vides basic prescription drug coverage  
24 or qualified prescription drug coverage  
25 that provides supplemental prescrip-

1                   tion drug coverage so long as there is  
 2                   no MA monthly supplemental bene-  
 3                   ficiary premium applied under the  
 4                   plan, due to the application of a credit  
 5                   against such premium of a rebate  
 6                   under section 1854(b)(1)(C).”;

7                   (B) in paragraph (2)(A), by striking “sec-  
 8                   tion 1860D–3(a)” and inserting “paragraph  
 9                   (1)(B)”;

10                  (C) in subparagraphs (A) and (B) of para-  
 11                  graph (4), by striking “fallback prescription  
 12                  drug plan” each place it appears and inserting  
 13                  “medicare operated plan option”.

14                  (3) Section 1860D–11(h) is amended—

15                   (A) in the heading, by striking “AND  
 16                   FALLBACK PLANS”;

17                   (B) by striking the first sentence and in-  
 18                   serting the following: “The Secretary shall sub-  
 19                   mit to Congress an annual report that describes  
 20                   instances in which limited risk plans were of-  
 21                   fered under subsection (f).”.

22                  (4) Section 1860D–12(b) of the Social Security  
 23                  Act, as added by section 101(a) of the Medicare Pre-  
 24                  scription Drug, Improvement, and Modernization  
 25                  Act of 2003 (Public Law 108–173), is amended—

1 (A) by striking paragraph (2); and

2 (B) by redesignating paragraph (3) as  
3 paragraph (2).

4 (5) Section 1860D–15 of the Social Security  
5 Act, as added by section 101(a) of the Medicare Pre-  
6 scription Drug, Improvement, and Modernization  
7 Act of 2003 (Public Law 108–173), is amended by  
8 striking subsection (g).

9 (c) EFFECTIVE DATE.—The amendments made by  
10 this section shall take effect as if included in the enact-  
11 ment of section 101(a) of the Medicare Prescription Drug,  
12 Improvement, and Modernization Act of 2003 (Public Law  
13 108–173).

14 **SEC. 3. NEGOTIATING FAIR PRICES FOR MEDICARE PRE-**  
15 **SCRIPTION DRUGS.**

16 Section 1860D–11 of the Social Security Act, as  
17 added by section 101(a) of the Medicare Prescription  
18 Drug, Improvement, and Modernization Act of 2003 (Pub-  
19 lic Law 108–173), is amended by striking subsection (i)  
20 (relating to noninterference) and by inserting the fol-  
21 lowing:

22 “(i) NEGOTIATION OF PRICES WITH MANUFACTUR-  
23 ERS.—In order to ensure that beneficiaries enrolled under  
24 prescription drug plans and MA–PD plans pay the lowest  
25 possible price, the Secretary shall—



1           “(1) have authority similar to that of other  
 2       Federal entities that purchase prescription drugs in  
 3       bulk to negotiate contracts with manufacturers of  
 4       covered part D drugs, consistent with the require-  
 5       ments and in furtherance of the goals of providing  
 6       quality care and containing costs under this part;  
 7       and

8           “(2) use such authority to negotiate the prices  
 9       of covered part D drugs furnished to part D eligible  
 10      individuals under prescription drug plans offered by  
 11      PDP sponsors under this part.”.

12 **SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS.**

13       Section 804 of the Federal Food, Drug, and Cosmetic  
 14      Act (21 U.S.C. 384) is amended—

15           (1) in subsection (a)—

16               (A) by striking “The Secretary” and in-  
 17               serting “Not later than 180 days after the date  
 18               of enactment of the Pharmaceutical Market Ac-  
 19               cess Act of 2003, the Secretary”; and

20               (B) by striking “pharmacists and whole-  
 21               salers” and inserting “pharmacists, wholesalers,  
 22               and qualifying individuals”;

23           (2) in subsection (b)—

24               (A) by striking paragraph (1) and insert-  
 25               ing the following:

1           “(1) require that each covered product imported  
 2           under that subsection complies with sections 501,  
 3           502, and 505 and other applicable requirements of  
 4           this Act; and”;

5                   (B) in paragraph (2), by striking “, includ-  
 6                   ing subsection (d); and” and inserting a period;  
 7                   and

8                   (C) by striking paragraph (3);

9           (3) in subsection (c), by inserting “by phar-  
 10          macists and wholesalers (but not qualifying individ-  
 11          uals)” after “importation of covered products”;

12          (4) in subsection (d)—

13                   (A) by striking paragraphs (3) and (10);

14                   (B) in paragraph (5), by striking “, includ-  
 15                   ing the professional license number of the im-  
 16                   porter, if any”;

17                   (C) in paragraph (6)—

18                           (i) in subparagraph (C), by inserting  
 19                           “(if required under subsection (e))” before  
 20                           the period;

21                           (ii) in subparagraph (D), by inserting  
 22                           “(if required under subsection (e))” before  
 23                           the period; and

24                           (iii) in subparagraph (E), by striking  
 25                           “labeling”;

1 (D) in paragraph (7)—

2 (i) in subparagraph (A), by inserting  
3 “(if required under subsection (e))” before  
4 the period; and

5 (ii) by striking subparagraph (B) and  
6 inserting the following:

7 “(B) Certification from the importer or  
8 manufacturer of the product that the product  
9 meets all requirements of this Act.”; and

10 (E) by redesignating paragraphs (4)  
11 through (9) as paragraphs (3) through (8), re-  
12 spectively;

13 (5) by striking subsection (e) and inserting the  
14 following:

15 “(e) TESTING.—

16 “(1) IN GENERAL.—Subject to paragraph (2),  
17 regulations under subsection (a) shall require that  
18 testing referred to in paragraphs (5) through (7) of  
19 subsection (d) be conducted by the importer of the  
20 covered product, unless the covered product is a pre-  
21 scription drug subject to the requirements of section  
22 505B for counterfeit-resistant technologies.

23 “(2) EXCEPTION.—The testing requirements of  
24 paragraphs (5) through (7) of subsection (d) shall

1 not apply to an importer unless the importer is a  
2 wholesaler.”;

3 (6) in subsection (f), by striking “or designated  
4 by the Secretary, subject to such limitations as the  
5 Secretary determines to be appropriate to protect  
6 the public health”;

7 (7) in subsection (g)—

8 (A) by striking “counterfeit or”; and

9 (B) by striking “and the Secretary deter-  
10 mines that the public is adequately protected  
11 from counterfeit and violative covered products  
12 being imported pursuant to subsection (a)”;

13 (8) in subsection (i)(1)—

14 (A) by striking subparagraph (A) and in-  
15 serting the following:

16 “(A) STUDY.—

17 “(i) IN GENERAL.—The Secretary  
18 shall conduct, or contract with an entity to  
19 conduct, a study on the imports permitted  
20 under subsection (a), including consider-  
21 ation of the information received under  
22 subsection (d).

23 “(ii) EVALUATION.—In conducting  
24 the study, the Secretary or entity shall—

1 “(I) evaluate the compliance of  
 2 importers with regulations under sub-  
 3 section (a), and the incidence of ship-  
 4 ments under that subsection, if any,  
 5 that have been determined to be mis-  
 6 branded or adulterated; and

7 “(II) determine how that compli-  
 8 ance contrasts with the incidence of  
 9 shipments of prescription drugs trans-  
 10 ported within the United States that  
 11 have been determined to be mis-  
 12 branded or adulterated.”; and

13 (B) in subparagraph (B), by striking “Not  
 14 later than 2 years after the effective date of  
 15 final regulations under subsection (a),” and in-  
 16 serting “Not later than 18 months after the  
 17 date of enactment of the Pharmaceutical Mar-  
 18 ket Access Act of 2003,”;

19 (9) in subsection (k)(2)—

20 (A) by redesignating subparagraphs (D)  
 21 and (E) as subparagraphs (E) and (F), respec-  
 22 tively; and

23 (B) by inserting after subparagraph (C)  
 24 the following:

1                   “(D) QUALIFYING INDIVIDUAL.—The term  
2                   ‘qualifying individual’ means an individual who  
3                   is not a pharmacist or a wholesaler.”; and  
4                   (10) by striking subsections (l) and (m).

5   **SEC. 5. LIMITATION ON PRESCRIPTION DRUG BENEFITS OF**  
6                   **MEMBERS OF CONGRESS.**

7           (a) LIMITATION ON BENEFITS.—Notwithstanding  
8   any other provision of law, the actuarial value of the pre-  
9   scription drug benefits of any Member of Congress en-  
10   rolled in a health benefits plan under chapter 89 of title  
11   5, United States Code, may not exceed the actuarial value  
12   of basic prescription drug coverage (as defined in section  
13   1860D–2(a)(3) of the Social Security Act, as added by  
14   section 101(a) of the Medicare Prescription Drug, Im-  
15   provement, and Modernization Act of 2003 (Public Law  
16   108–173)).

17          (b) REGULATIONS.—The Director of the Office of  
18   Personnel Management shall promulgate regulations to  
19   carry out this section.

○